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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,594	08/25/2000	Malcolm King	11157-14	4598

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EXAMINER
WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
1617	22

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/645,594	KING, MALCOLM	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,27 and 28* is/are pending in the application.

4a) Of the above claim(s) *27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-19 and 27-28 are pending. Claims 27-28 are withdrawn from consideration. The Amendment filed 6/18/03, Paper No. 21, amended claims 1, 7, 10 and 15.

Applicant's Amendment filed 6/18/03, Paper No. 21, is sufficient to overcome the 35 USC 112 rejection in the previous Office Action.

Election/Restrictions

Applicant's affirmation of the election of Group I in Paper No. 21 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "in an animal that does not have a respiratory tract bacterial infection and not for the purposes of treating a respiratory tract bacterial infection" is new and not supported by the original disclosure.

Regarding this rejection, Applicant argues, "The Applicant respectfully notes that the Examples in the present application involve studies in healthy dogs, which were free from bacterial infections, and show the value of dextran sulfate administration in providing the rheological properties of airway mucus to make it more easily clearable by ciliary and airflow mechanisms in non-bacterial infection environments. A person skilled in the art would understand that "healthy dogs" would be free of bacterial infections. These Examples support the use of dextran sulfate as a mucoactive agent to improve airway clearance, independent of the role of bacterial infection". This argument is not persuasive. First, it is respectfully pointed out that the recitation of a healthy dog does not mean that the dog is free from bacterial infection. Second, it is pointed out that even if there was support for a dog without a bacterial infection, that does not provide support for any animal without bacterial infection, as recited in the instant claims. Third, it is pointed out that the specification provides absolutely no support for not using dextran sulfate for the purposes of treating a respiratory bacterial infection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-5, 7-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speert et al. (5,514,665).

The instant invention is directed to a method of administering to the mucus, an effective amount of charged dextran.

Speert et al. teach a method of administering a composition comprising dextran or dextran sulfate to cystic fibrosis patients. Specifically taught are methods for reducing the risk of or preventing infections by bacterial pathogens in vivo. An aerosol, wherein administration is via inhalation, is a disclosed form of the composition. A dosage of 10-20mmol of dextran sulfate is disclosed, wherein 20mmol is 160mg/ml of dextran sulfate in solution. The reference lacks the explicit step of administering dextran sulfate to mucus. See Col. 4, line 30-line 55; Col. 5, line 11-Col. 7, line 26; Col. 9, line 63-Col. 12, line 11.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the method of Speert et al. wherein the composition comprising dextran sulfate is administered to mucus because a) Speert et al. teach their compositions as being administered to Cystic Fibrosis patients, and Webster's Dictionary defines Cystic Fibrosis as 'a common hereditary disease especially among whites that appears usually in early childhood, involves functional disorder of the exocrine glands, and is marked especially by faulty digestion due to a deficiency of pancreatic enzymes, by difficulty in breathing due to ***mucus accumulation in airways***, and by excessive loss of salt in the sweat'; b) administration of an aerosol composition, via inhalation, is directly administered to the respiratory tract; thus, one of skill in the art would have taught the method of Speert et al. as administering a dextran sulfate composition to the mucus because Cystic Fibrosis patients have mucus in their airways and aerosol inhalation administers active agents to the respiratory tract.

The claims are directed to a method of decreasing viscoselasticity of respiratory tract mucus in an animal that does not have a respiratory tract bacterial infection and not for the purposes of treating a respiratory tract bacterial infection comprising administering to the

respiratory tract mucus of said animal an effective amount of charged dextran. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches administration of compositions containing the same components as instantly claimed, which would inherently decrease viscoselasticity of respiratory tract mucus in an animal that does not have a respiratory tract bacterial infection and not for the purposes of treating a respiratory tract bacterial infection as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

It is respectfully pointed out that a method of preventing infections means that the compositions are administered to patients that do not have bacterial infections and thus the purpose is to prevent the infection and not to treat the infection.

Claims 3, 6, 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speert et al. as applied to claims 1-2, 4-5, 7-17 above, and further in view of Kennedy (WO 91/15216).

Speert et al. is applied as discussed above. The reference lacks preferred molecular weights of dextran sulfate.

Kennedy teaches a method of applying a polysulphated polysaccharide to a host via aerosolization, wherein dextran sulfate is disclosed as a polysulfated polysaccharide. Dextran

sulfate is disclosed as having a molecular weight of less than 10,000 and as preferably 5000 or 8000. See pg. 8, line 22-pg. 9, line 25; pg. 18-19.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the dextran sulfate of Speert et al. as having a molecular weight of 5000, as taught by Kennedy, because a) Speert and Kennedy teach the same method of administering the same composition; and b) it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980); thus, one of skill in the art would be motivated to teach the dextran sulfate of Speert et al. as having a molecular weight of 5000.

Response to Arguments

Applicant argues, "The properties of dextran sulfate with respect to respiratory tract mucus are novel and independent of its properties as described in relation to bacterial infections in Speert et al. and Kennedy". This argument is not persuasive. As described in the above rejection, the method taught by Speert et al. does not exclusively teach administering dextran sulfate to patients with bacterial infections. Furthermore, it is respectfully pointed out that Applicant has provided no evidence or persuasive arguments as to why a compound administered in the same way to the same population of patients, as that of the instant invention, would not have the same properties.

Applicant argues, "There are no examples of application of the dextran sulfate to the respiratory tract or to respiratory tract mucus. As such, this indicates that the dextran sulfate in Speert et al. is working on sites of bacterial adhesion and not on respiratory tract mucus". This argument is not persuasive. First, the Examiner respectfully points out that it is well-established

that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983). Second, the Examiner respectfully points out that Speert et al. teach administering their dextran composition in the form of an aerosol, wherein aerosols, via inhalation, are administered to the respiratory tract and hence, to the mucus.

Applicant argues, "Kennedy teaches the effect of dextran sulfate on HLE and HLE substrate interaction and not on respiratory tract mucus". This argument is not persuasive, as Kennedy is merely relied upon to teach the preferred percent weights of dextran sulfate.

Applicant argues, "Although, the description states that the dextran sulfate can be administered by aerosol, no examples are provided an no examples of administration to respiratory tract mucus are provided as all examples and the description emphasize application to the cellular sites of bacterial adhesion". This argument is not persuasive. Again the Examiner respectfully points out that it is well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. Second, the Examiner respectfully points out that Speert et al. does not exemplify any method.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw

SREENI PADMANABHAN
PRIMA ...ER 9/22/03